

### ***REMARKS***

This responds to the Office Action dated December 13, 2004. The Office Action was a final action.

The Office Action indicates that applicant's previous arguments with respect to the claims of the application were considered but that they are moot in view of the new grounds of rejection. The new grounds of rejection added another patent to the combination of patents previously used by the Examiner to reject the claims.

Applicant submits that the foregoing amendments and the following remarks could not have been presented earlier during the prosecution of this application because the various objections and rejections were newly presented in the final action. Accordingly, applicant requests that this Amendment be entered in the application for purposes of appeal. Also, applicant requests that the Amendments and statements concerning patentability of the invention be considered for allowing the claims of the application.

#### **Specification**

The Amendment filed 30 August 2004 was objected to under § 132 because it introduces new matter into the disclosure. The language specifically objected to as including new matter has been deleted from the specification. Certain original parts of the specification have been restored so that no new matter exists.

Accordingly, applicant requests that the objection to the specification be withdrawn.

#### **Rejections - 35 U.S.C. § 112**

Claims 64 and 75 were rejected under § 112, first paragraph, as failing to comply with the written description requirement. Claims 64 and 75 erroneously included the expression of "twelve o'clock position" when the expression should have been --six o'clock position--. Accordingly, these claims have been amended to properly reflect the position of the handle of the anoscope, as the Examiner pointed out. These positions were properly described in original claims 19 and 20. Also, the inversion of the positions of the openings in the anoscope with the handle inverted is set forth in other claims of the application. Accordingly, the modification to correct claims 64 and 75

does not present a new issue for consideration by the Examiner and does not require additional search by the Examiner. Accordingly, entry of the amendments to claims 64 and 75 is requested.

### **Features of the Invention**

This invention addresses a need in the industry to provide a ligator and anoscope system that provides access to the locations of multiple internal hemorrhoids and simultaneously supplies multiple rubber bands for ligation of multiple hemorrhoids, without necessitating multiple retractions and reinsertions of the ligator and the anoscope. (Specification, page 2, lines 27-30.) Applicant's anoscope is utilized to expose all three internal hemorrhoids simultaneously. The apertures of the anoscope are located at the three, seven, and eleven o'clock positions, which are the normal anatomic locations of internal hemorrhoids in man. Thus, the anoscope is configured to expose all three internal hemorrhoids simultaneously. In this respect, having once inserted the anoscope, all three internal hemorrhoid locations are accessible by virtue of the location of the lateral apertures in the anoscope. Thus, discomfort from repeated insertions of the anoscope and its ligator are minimized. (Specification, pages 4, 5, lines 20-4.)

In man, the three internal hemorrhoids are located at fairly constant locations within the anal canal: left lateral, right anterior, and right posterior positions. These positions are equivalent to the three, seven and eleven o'clock locations with the patient in the supine position. Other prior art anoscopes generally are configured to either expose only one hemorrhoid location at a time or are configured with a plurality of apertures that are not oriented in accordance with the hemorrhoid positions. When using an anoscope having only one aperture, the placement of the anoscope must be precise and movement to expose other hemorrhoids requires the retraction and reinsertion of the anoscope. For anoscopes having a plurality of apertures, careful placement is also required to expose as many of the multiple hemorrhoids as possible. The imprecise placement of the prior art anoscopes requires retraction and reinsertion or adjustment of the device internally, both of which are time consuming and result in discomfort to the patient. (Specification, page 10, lines 1-10.)

The three aperture configuration of the present anoscope addresses the deficiencies of the prior art. The anoscope has three lateral apertures 59A, 59B and 59C, located at the three, seven and eleven o'clock positions. These are the positions of the normal anatomic location of the internal hemorrhoids in a patient. Thus, using applicant's anoscope, a single insertion of the

anoscope therefore allows simultaneous access to all three internal hemorrhoids. (Specification, page 10, lines 19-29.)

A handle 51 extends from the proximal flange or shoulder 54 of the anoscope and extends at an angle away from the longitudinal axis of the anoscope. The handle 51 provides a means of inserting, withdrawing and rotating the anoscope. The location of the handle 51 in relation to the anoscope 50 may be in the twelve o'clock or six o'clock positions in order to assure proper positioning of the apertures of the anoscope to the corresponding hemorrhoid locations in man. When the handle is configured in the twelve o'clock position relative to the anoscope 50, the apertures 59A, 59B and 59C of the anoscope 50 are correctly oriented in relation to the internal hemorrhoids for a patient in the prone position. Alternatively, when handle 51 is completely in the six o'clock position, the apertures 59A, 59B and 59C of the anoscope 50 are correctly oriented in relation to the internal hemorrhoids for a patient in the prone position. (Specification, page 11, lines 1-16.)

#### **Claim Rejections - 35 U.S.C. § 103**

Claims 26-35, 55-63, 65-74, 76 and 77 were rejected under § 103(a) as being unpatentable over Watson, Jr., et al. (5,788,715) in view of Bayer (6,126,594), and further in view of Bidoia (5,203,863).

The rejection indicates that Watson, Jr., et al. teaches the system for ligation of internal hemorrhoids but no anoscope or loading cone is disclosed, and Bayer teaches the anoscope, and Bidoia discloses the loading mechanism that allows multiple rubber bands to be placed in the cylinder of Watson.

Bayer discloses an anoscope that does not have its openings properly oriented for revealing the hemorrhoids simultaneously. The openings of Bayer are not oriented at the three o'clock, seven o'clock, and eleven o'clock positions, as described. Accordingly, it appears that the Bayer anoscope would have to be repositioned so as to expose one hemorrhoid to the next. This would likely require withdrawing the anoscope, reorienting the anoscope and then reinserting the anoscope, to the discomfort of the patient.

Claim 26 describes the anoscope as follows:

--wherein the anoscope is configured with a hollow cylinder with multiple apertures formed about the hollow cylinder at positions about the hollow cylinder for *simultaneously* exposing hemorrhoids in the anal canal *at the normal anatomic locations of the hemorrhoids* in a patient and *permitting simultaneous access to the normal locations for internal hemorrhoids*;

Bayer does not do this. The other prior art of record and the prior art known to applicant does not do this. Accordingly, claim 26 should be in condition for allowance.

Claim 27 specifies that the apertures are three apertures, with those three apertures configured to correspond to normal hemorrhoid locations in the patient, thus permitting simultaneous access. This claim also adds the apertures of the anoscope extending approximately halfway along the length of the anoscope. This provides the feature of locating an isolating hemorrhoids without having other portions of the anal canal protrude inwardly into the anoscope and forming an obstacle to the position.

Claims 28 –35 depend from independent claim 26 and include all the limitations thereof. Accordingly, these dependent claims should be in condition for allowance.

Independent claim 55 includes:

--said cylinder (of the anoscope) defining three lateral apertures extending along said cylinder opening from the distal end of said cylinder toward the proximal end of the cylinder, said apertures being spaced apart about said cylinder to be *positionable at the three o'clock, seven o'clock and eleven o'clock* positions about the cylinder when inserted in the anal canal with the patient in the supine position.—

The applied references do not disclose the above noted feature. The anoscope as described in claim 55 is constructed differently from the Bayer anoscope and provides an improved result. Accordingly, claim 55 should be in condition for allowance.

Dependent claims 56-65 refer back to and include the limitations of independent claim 55 and should be in condition for the same reasons.

Independent claim 66 includes:

--said cylinder defining three lateral apertures opening from the distal end of said cylinder toward the proximal end of said cylinder, said apertures being spaced apart about said cylinder *to be positionable at the three o'clock, seven o'clock and eleven o'clock* positions about the cylinder when inserted in the anal canal with

*the patient in the supine position for exposing three areas of the anal canal that have internal hemorrhoids.*

The above noted features of the invention are not disclosed or suggested by Bayer. While Bayer has multiple apertures, they are not disclosed as being in the locations specifically described in the claims of this application. Bayer does state that his anoscope provides convenient access to any number of hemorrhoids at any angle. (Column 1, lines 62-67.) However, this does not provide simultaneous access as described by applicant and as set forth in the claims of the application. Bayer also states that the spacing of the strips that form the openings may be variable, if desired. (Column 3, lines 1-7.) However, Bayer does not disclose applicant's concept of an anoscope with properly spaced openings for achieving applicant's result of simultaneous and exclusive access to the hemorrhoids.

Dependent claim 69 has the feature of the apertures extending approximately halfway along the length of the cylinder of the anoscope to expose internal hemorrhoids while the rest of the cylinder tends to hold other features of the anal canal outside the cylinder. Again, this is not disclosed or suggested by Bayer.

Dependent claim 70 describes the features of the apertures not extending more than halfway along the length of the cylinder to expose only internal hemorrhoids in the anal canal. Again, not disclosed in Bayer.

Dependent claim 74 adds the feature of the handle oriented in the twelve o'clock position with the openings in the anoscope cylinder oriented in the three, seven and eleven o'clock positions, with the patient in the supine position. This is not disclosed or made obvious by Bayer.

Dependent claim 75 is similar to 74, but the orientation of the openings are inverted when the patient is in the inverted or prone position.

Independent claim 77 sets forth:

*--said cylinder defining lateral apertures--spaced apart about said cylinder to register with the internal hemorrhoids of a patient,  
a handle extending--at a predetermined angle with respect to the apertures of the cylinder such that--the handle is oriented at a predetermined attitude with respect to the patient the apertures of the cylinder register with the internal hemorrhoids of the patient.--*

Again, these features of claim 77 are not suggested, taught, or made obvious by the cited references.

### **Conclusions in the Final Action**

The Final Action indicates that Bayer teaches an anoscope with apertures at positions about the hollow cylinder for simultaneously exposing hemorrhoids in the anal canal and cites column 1, lines 63-64. However, this portion of the Bayer specification states:

The anoscope provides convenient access to any number of hemorrhoids at any angle.

This does not support the conclusion that the Bayer anoscope simultaneously exposes the hemorrhoids. If the strips 22 of Bayer are in the wrong place, when one opening of Bayer registers with a hemorrhoid, the other openings may or may not register with another hemorrhoid. The disclosure of Bayer does not teach that the openings of his anoscope will simultaneously disclose hemorrhoids at the normal anatomic locations of the internal hemorrhoids of man: the 3 o'clock, 7 o'clock and 11 o'clock positions. Indeed, it appears from the drawing that the multiple openings between the strips 22 of Bayer are for the purpose of having to rotate the Bayer anoscope so as to conveniently register one hemorrhoid after the other with the openings.

The Office Action argues that it would have been obvious to one having ordinary skill in the art to make the anoscope of Bayer as recited in the claims because the dimensions of the anoscope are a mere design choice. Applicant strongly disagrees. The dimensions are more than a design choice. The dimensions provide the ability of applicant's anoscope to be used as a grading device, to grade the size of the hemorrhoids in a quantitative manner. (Specification, page 11, lines 17-29.) Specific grading information is provided in the specification. The specific dimensions become important and solve the stated problems and have a major purpose, and this would not result from use of the Bayer anoscope.

**Bayer does not identify hemorrhoids in the proper anatomical locations and does not match his anoscope to those locations.**

Applicant requests favorable reconsideration of the application. Specifically, please enter the Amendment in the application so that prosecution of the application can be properly advanced.

Respectfully submitted,

  
George M. Thomas, Reg. No. 22,260 1/24/05

**THOMAS, KAYDEN,**  
**HORSTEMEYER & RISLEY, L.L.P.**  
Suite 1750  
100 Galleria Parkway N.W.  
Atlanta, Georgia 30339  
(770) 933-9500